

NOV 5 1998

K983287

Letter to
Regulatory
Bureau
Date:

510(k) SUMMARY



Date:

September 16, 1998

Graphic Controls

Manufacturing Facility:

Graphic Controls Corporation
189 Van Rensselaer Street
P.O. Box 1271
Buffalo, NY 14240
Registration Number 1317188

Telephone:

(716) 853-7500

Contact Person:

Kathleen Selover
Regulatory Affairs Specialist
(716) 853-7500, extension 7630
Fax: (716) 847-7531

Device Trade Name:

Medi-Trace® 1610C Combination Defibrillation,
Monitoring and Pacing Electrode

Device Common Name:

Self Adhesive Defibrillation and Monitoring
Electrode

Classification Name:

Electrode, Electrocardiograph, Multifunction

Regulatory Reference:

~~74~~MLN

Predicate Device:

Cardiotronics Systems, Inc., a division of Ballard
Medical Products, R2® Pads™ Pacing/Defibrillation
and ECG Electrode

Description:

A pre-gelled conductive electrode consisting of a pre-attached leadwire, and insulating layer of a vinyl substrate, a secondary vinyl piece covering the crimped wire connector, a layer of metal foil, a conductive adhesive hydrogel, a pressure sensitive adhesive (PSA) ring and a release liner. Device is packaged in pairs in a heat sealed pouch; 10 pouches are packaged into one shelf box shipper.

| | |
|---------------------------------------|---|
| Intended/Indications for Use: | Intended for use in defibrillation procedures, cardioversion and pacing. This device is intended for use on adults. |
| Physical/Technical Comparison: | Medi-Trace® 1610C Electrode is replaceable with the Cardiotronics, Inc, a division of Ballard Medical Products, R2® Pads™ Pacing/Defibrillation/ECG Electrodes. Physical and technical characteristics, including materials used in construction, size, intended use and conductive gel type of these electrodes are comparable. Since the formulation of conductive gel of the predicate is considered to be proprietary, exact chemical comparison could not be made. |
| Performance Summary: | <p>The device and the predicate were subject to AAMI electrical tests as described in DF-39, 3.3.19 and energy through put testing. Test results for both the device and the predicate meet the specifications as established in DF-39 for self adhesive electrodes for monitoring and defibrillation and pacing.</p> <p>In addition, the device was subjected to simulated use testing consisting of multiple defibrillation shocks, maximum current pacing and ECG monitoring. Test results for the device met the specifications as established in DF-39 for self adhesive electrodes for monitoring, defibrillation and pacing.</p> |
| Biocompatibility Testing: | The device was subjected to biocompatibility testing as recommended in <i>ISO-10993, Biological Evaluation of Medical Devices Part I: Evaluation and Testing.</i> The device was found to be non-irritating, non-cytotoxic and non-sensitizing. |
| Shelf Life: | Data obtained in accelerated shelf life studies were reviewed and found to substantiate our claimed shelf life. |



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 5 1998

Susan A. Krasny, Ph.D.
Graphic Controls Corporation
189 Van Rensselaer Street
P.O. Box 1271
Buffalo, NY 14240-1271

Re: K983287
Medi-Trace® 1610C Combination Defibrillation, Monitoring and
Pacing Electrode
Regulatory Class: III (Three)
Product Code: 74 MLN
Dated: September 16, 1998
Received: September 18, 1998

Dear Dr. Krasny:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, reading "Thomas J. Callahan". The signature is fluid and cursive, with the first letters of the first and last names being capitalized and prominent.

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Page 1 of 1510(k) Number, if known: K983287Device Name: Medi-Trace® 1610C Combination Defibrillation,
Monitoring and Pacing Electrode

Indications for Use:

The Medi-Trace® 1610C Combination Defibrillation, Monitoring and Pacing Electrode is intended for use in defibrillation procedures, cardioversion, pacing and ECG monitoring on adults.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE
IF NEEDED)

_____ Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark Kramer

Prescription Use ☒ OR Over-the-Counter Use _____ (Per 21CFR 801.109)

(Division Sign-Off)

Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number _____